K090689

MAQUET

OCT 29 2009

510 (K) Summary [as required by 21 CFR 807.92(c)]

Submitter:	MAQUET Cardiopulmonary AG Hechinger Strasse 38 72145 Hirrlingen Germany
Contact Person:	Dr. Ingrid Richter Phone: +49 7478 921-337 Fax: +49 7478 921-400 E-mail: ingrid.richter@maquet-cp.com
Date Prepared:	March 10, 2009
Device Trade Name:	QUADROX-i Small Adult Microporous Membrane Oxygenator with and without Integrated Arterial Filter with Softline Coating
Common/Usual name:	Oxygenator with integrated heat exchanger and optional integrated arterial filter
Classification names:	Oxygenator, cardiopulmonary bypass Heat Exchanger, cardiopulmonary bypass Filter, blood, cardiopulmonary bypass, arterial line
Predicate Devices:	QUADROX-i Adult Microporous Membrane Oxygenator with and without Integrated Arterial Filter with Softline Coating (art. code HMO 70000/71000), K082117, manufactured by MAQUET Cardiopulmonary AG Quart Arterial Filter (art.code HBF 140), K001787 by MAQUET Cardiopulmonary AG and Capiox RX15 Hollow Fiber Oxygenator with/without Hardshell Reservoir with X-Coating from Terumo Cardiovascular Systems Corp., K051997

Device Description:

The QUADROX-i Small Adult is a blood-gas exchanger with integrated heat exchanger and optionally integrated arterial blood filter.

The QUADROX-i Small Adult may be marketed both as single product and pre-mounted with the venous hardshell cardiotomy reservoir (K003551, K982136).

Indications for Use:

The membrane oxygenator QUADROX-i Small Adult is intended for the use in extracorporeal circulation during cardiopulmonary bypass in cardiac surgery. The blood flow rate is defined from 0.5 – 5 L/min. Within the specified flow rate range, the device oxygenates the blood, eliminates carbon dioxide and regulates blood temperature. The QUADROX-i Small Adult (HMO 51000) version with integrated arterial filter also filters out air bubbles and particles larger than 40 µm. The device's utilization period is limited to six hours.
The oxygenator is suitable for the delivery of the volatile anesthetics isoflurane and sevoflurane. The anesthetic gas is administered through the oxygenator's gas inlet by means of a suitable anesthetic gas vaporizer.
Responsibility for deciding whether to use an oxygenator rests solely with the attending physician.

Statement of Technical Comparison:

The QUADROX-i Small Adult Microporous Membrane Oxygenator with and without Integrated Arterial Filter with Softline Coating is well comparable to the QUADROX-i Adult Microporous Membrane Oxygenator with and without Integrated Arterial Filter with Softline Coating (art. code HMO 70000/71000), K082117, manufactured by MAQUET Cardiopulmonary AG regarding the design, principals of operation, biocompatibility and performance as well as regarding the Softline coating, the only difference is the size. It is also comparable to Capiox RX15 Hollow Fiber Oxygenator with/without Hardshell Reservoir with X-Coating from Terumo Cardiovascular Systems Corp., K051997, regarding intended use, as well as to the Quart Arterial Filter as related to the filter part.

Non-clinical Testing:

The QUADROX-i Small Adult Microporous Membrane Oxygenator with and without Integrated Arterial Filter with Softline Coating has been tested to and met the requirements of ISO 10993-1 Biologic Evaluation of Medical Devices as well as the requirements of ISO 7199: 1996 "Cardiovascular implants and artificial organs – blood gas exchangers (oxygenators) as well as the requirements of ISO 15675: 2001 "Cardiovascular implants and artificial organs – Cardiopulmonary Bypass – Arterial line blood filters".

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Determination of Substantial Equivalence

Testing and evaluation on safety and effectiveness was executed to demonstrate that the QUADROX-i Small Adult Microporous Membrane Oxygenator with and without Integrated Arterial Filter with Softline Coating described in this submission is substantially equivalent to Capiox RX15 Hollow Fiber Oxygenator with/without Hardshell Reservoir with X-Coating from Terumo Cardiovascular Systems Corp., K051997, as related to the intended use, as well as to the Quart Arterial Filter (HBF 140), K001787, as related to the filter part.
It is also comparable to the QUADROX-i Adult Microporous Membrane Oxygenator with and without Integrated Arterial Filter with Softline Coating (art. code HMO 70000/71000), K082117 regarding the constructional principle as well as the coating.

The following areas have been tested:

- Integrity
- Performance
- Biocompatibility
- Sterility

Conclusion

The data given demonstrate that the QUADROX-i Small Adult Microporous Membrane Oxygenator with and without Integrated Arterial Filter with Softline Coating is substantially equivalent to the named predicate devices which currently hold market clearance.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room W-O66-0609
Silver Spring, MD 20993-0002

Maquet Cardiopulmonary AG
c/o Dr. Ingrid Richter
Regulatory Affairs Manager
Hechinger Strasse 38
D-72145 Hirringen
Germany

OCT 2 9 2009

Re: K090689
QUADROX-i Small Adult Microporous Membrane Oxygenator with and without Integrated Arterial Filter with Softline Coating
Regulation Number: 21 CFR 870.4350
Regulation Name: Oxygenator, Cardiopulmonary Bypass
Regulatory Class: Class II
Product Code: DTZ
Dated: October 16, 2009
Received: October 19, 2009

Dear Dr. Richter:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

for Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K090689

QUADROX-i Small Adult Microporous Membrane Oxygenator with and without Integrated Arterial Filter with Softline Coating _____

Indications for Use:

The membrane oxygenator QUADROX-i Small Adult is intended for the use in extracorporeal circulation during cardiopulmonary bypass in cardiac surgery. The blood flow rate is defined from 0.5 – 5 L/min. Within the specified flow rate range, the device oxygenates the blood, eliminates carbon dioxide and regulates blood temperature. The QUADROX-i Small Adult (HMO 51000) version with integrated arterial filter also filters out air bubbles and particles larger than 40 µm. The device's utilization period is limited to six hours.

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Prescription Use ___X___ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Cardiovascular Devices

510(k) Number K090689

(Posted November 13, 2003)